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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,524	07/07/2006	Per Munk Nielsen	10578.204-US	7930

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NOVOZYMES NORTH AMERICA, INC.
500 FIFTH AVENUE
SUITE 1600
NEW YORK, NY 10110

EXAMINER

WILLIAMS, LELA

ART UNIT	PAPER NUMBER
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1789

NOTIFICATION DATE	DELIVERY MODE
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07/08/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

Office Action Summary	Application No. 10/585,524	Applicant(s) NIELSEN, PER MUNK	
	Examiner LELA S. WILLIAMS	Art Unit 1789	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 17-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/6/2011</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 6, 2011 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. **Claim 1, 3, 5, 6, 7, 11, 14, 17, 18, 19, 20, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winterbottom et al CH Patent No. 356,659.**

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Winterbottom et al. discloses a method for producing a food product which comprises contacting meat with a solution containing lactobionic acid (pg. 2, lines 15-20 & pg. 3, line 24, pg. 4, line 16). Slaughtered poultry is submerged into the lactobionic acid containing solution, for a time of 30 minutes to 4 hrs (marinate), and allowed to freeze; the poultry is then packed and distributed to the market place (pg.1, lines 26-31 & pg. 5, lines 18-22). Winterbottom also discloses the poultry will be cooked (pg. 5, line 9), therefore becoming heated.

Although Winterbottom discloses that the flesh of the poultry “absorbs sufficient antibiotic matter to guarantee adequate protection” (pg. 6, line 24-26), the reference does not expressly disclose the amount of lactobionic acid absorbed or that the amount is “sufficient to reduce the water loss upon freezing and subsequent thawing of the meat based food product by 2% or more compared to the water loss of a similar food product prepared without lactobionic acid”. However, given that the poultry is soaked for at least 30 minutes in 3-30% lactobionic acid, and the references disclosure of a sufficient amount is absorbed; it is clear, absent any clear and convincing evidence to the contrary, that said sufficient amount would include 0.1-20% and which would be “sufficient to reduce the water loss upon freezing and subsequent thawing of the meat based food product by 2% or more compared to the water loss of a similar food product prepared without lactobionic acid”.

Furthermore, given that the product of claims 1, 19, 20, and 21 depends on the infusing process; it would have been within the ambit of one of ordinary skill to proceed with the infusion process until the meat contains the desired weight percentage of each component. In addition, since the product of claims 1, 19, 20, and 21 depend on variables which can be modified, such as the length of time of infusion and temperature, and the amount of components used in preparing

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the stock solution, which Winterbottom discloses would vary because cost of the constituents is a factor (col. 3, lines 72-75); one of ordinary skill in the art would easily determine acceptable amounts, including those which are presently claimed, through routine experimentation. As such, as set forth in MPEP § 2144.05, discovering an optimum value of a result effective variable, involves only routine skill in the art." and would not warrant patentability.

5. Claims 1, 3, 5, 6, 7, 11, 14, 17, 18, 19, 20, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable by Winterbottom et al. U.S Patent No. 2,930,702.

Winterbottom et al. discloses a method for producing a food product which comprises contacting meat with lactobionic acid (col. 1, line 15, col. 2, line 10, & col. 3, line 1). Slaughtered poultry is submerged into an antibiotic solution containing lactobionic acid (col. 3, line 34) and allowed to freeze for at least 30 minutes, after which, the poultry is then packed and distributed to the market place (col. 4, lines 6-15). The poultry will be cooked (col. 3, line 70), therefore becoming heated.

Although Winterbottom discloses that the flesh of the poultry "absorbs sufficient antibiotic matter to guarantee adequate protection" (pg. 6, line 24-26), the reference does not expressly disclose the amount of lactobionic acid absorbed or that the amount is "sufficient to reduce the water loss upon freezing and subsequent thawing of the meat based food product by 2% or more compared to the water loss of a similar food product prepared without lactobionic acid". However, given that the poultry is soaked for at least 30 minutes in the lactobionic acid containing solution, and the reference's disclosure of a sufficient amount is absorbed; it is clear, absent any clear and convincing evidence to the contrary, that said sufficient amount would

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include 0.1-20% and would be “sufficient to reduce the water loss upon freezing and subsequent thawing of the meat based food product by 2% or more compared to the water loss of a similar food product prepared without lactobionic acid”.

Furthermore, given that the product of claims 1, 19, 20, and 21 depends on the infusing process; it would have been within the ambit of one of ordinary skill to proceed with the infusion process until the meat contains the desired weight percentage of each component. In addition, since the product of claims 1, 19, 20, and 21 depend on variables which can be modified, such as the length of time of infusion, temperature, and the amount of components used in preparing the stock solution, which Winterbottom discloses would vary because cost of the constituents is a factor (col. 3, lines 72-75); one of ordinary skill in the art would easily determine acceptable amounts, including those which are presently claimed, through routine experimentation. As such, as set forth in MPEP § 2144.05, discovering an optimum value of a result effective variable, involves only routine skill in the art." and would not warrant patentability.

6. Claims 2, 8-10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winterbottom et al. CH Patent No. 356,659 or Winterbottom et al. U.S Patent No. 2,930,702 in view of Roselle et al. U. S. Pat. No. 6,773,737.

Winterbottom is applied as discussed above in paragraphs 4 and 5. Both references are silent to applying lactobionate acid to minced, fish, or emulsified meat and the product being surimi. Both are also silent to the form of lactobionate acid.

Roselle discloses a method for treating food products with a solution containing calcium lactobionate (col. 1, line 45 & col. 6, line 63). The food product can be in the form of beef, pork,

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chicken, and shellfish. Ground (minced) beef or turkey and fish cakes (of which surimi would be consider since it is defined as "ground meat") and fish cakes are also disclosed, as well as emulsified meat product, such as bologna, hot dogs, and sausages (col. 11, lines 3-10).

Therefore, it would have been obvious to one of ordinary skill in the art to use a solution containing calcium lactobionate in minced meat or surimi, as disclosed by Roselle, in Winterbottom, given Roselle's teaching of the solution being effective in killing microorganisms in food (col. 10, lines 21-53).

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winterbottom et al. CH Patent No. 356,659 or Winterbottom et al. U.S Patent No. 2,930,702 in view of Halden et al. EP 0 354 262.

Winterbottom discloses treating a food product with a lactobionic acid containing solution, resulting in a meat product containing lactobionic acid. The references are silent concerning marinating the meat by tumbling, however given that Halden teaches marinating meat using tumbling procedures (pg. 2, line 26) along with it being a well known procedure in the art, it would have been obvious to one of ordinary skill to use said procedure since it is known to allow for more penetration of the desired marinade (pg. 2, line 32).

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winterbottom et al. CH Patent No. 356,659 or U.S Patent No. 2,930,702 in view of Hayashabira GB Patent No. 1 325 727.

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Winterbottom et al. discloses treating a food product with a lactobionic acid containing solution, resulting in a meat product containing lactobionic acid. The references are silent concerning how the lactobionic acid is produced. Hayashabira discloses producing lactobionic acid from lactose by enzymatic oxidation (pg. 1, lines 71-85). Therefore, it would have been within the ambit of one of ordinary skill to manufacture said acid enzymatically given it is a known formation source in the art.

Response to Arguments

9. Claims 1-14 and 17-21 are currently pending. Claims 15-16 are cancelled.

10. Applicants' amendments filed April 11, 2011 are sufficient to overcome the 35 U.S.C.

102(b) set forth in the previous Office Action. Therefore, the rejection has been withdrawn.

However, upon further consideration, new grounds of rejection are made under 35 U.S.C. 103(a) as being unpatentable over Winterbottom et al. CH Patent No. 356,659 and U.S. Patent No. 2,930,702. (See above).

11. Regarding applicants' remarks to Winterbottom not disclosing the presently claimed amounts of lactobionic acid, Winterbottom discloses that the flesh of the poultry "absorbs sufficient antibiotic matter to guarantee adequate protection" (pg. 6, line 24-26). It is noted that the reference does not expressly disclose the amount of lactobionic acid absorbed or that the amount is "sufficient to reduce the water loss upon freezing and subsequent thawing of the meat based food product by 2% or more compared to the water loss of a similar food product prepared without lactobionic acid". However, given that the poultry is soaked for at least 30 minutes in the lactobionic acid containing solution, and the reference's disclosure of a sufficient amount is absorbed; it is clear, absent any clear and convincing evidence to the contrary, that said sufficient

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amount would include 0.1-20% and would be “sufficient to reduce the water loss upon freezing and subsequent thawing of the meat based food product by 2% or more compared to the water loss of a similar food product prepared without lactobionic acid”.

Furthermore, given that the product of claims 1, 19, 20, and 21 depends on the infusing process; it would have been within the ambit of one of ordinary skill to proceed with the infusion process until the meat contains the desired weight percentage of each component. In addition, since the product of claims 1, 19, 20, and 21 depend on variables which can be modified, such as the length of time of infusion, temperature, and the amount of components used in preparing the stock solution, which Winterbottom discloses would vary because cost of the constituents is a factor (col. 3, lines 72-75). Although the reference disclosed *recommended* amounts, one of ordinary skill, with financial means, since Winterbottom states cost is “a major factor”, would have easily determined acceptable amounts, through routine experimentation, including those which are presently claimed. As such, as set forth in MPEP § 2144.05, discovering an optimum value of a result effective variable, involves only routine skill in the art.” and would not warrant patentability.

12. Applicant’s argument regarding Halden (EP 0 354 262), Hayashabira (GB 1 325 727) and Roselle (US 6,773,737) have been noted, and note that while Halden (EP 0 354 262), Hayashabira (GB 1 325 727) and Roselle (US 6,773,737) do not disclose all the features of the present claimed invention, they are used as teaching references, and therefore, it is not necessary for these secondary reference to contain all the features of the presently claimed invention, *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), *In re Keller* 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather these references teaches a certain concept,

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marinating meat using a tumbling procedure (Halden); producing lactobionic acid from lactose by enzymatic oxidation (Hayashabira); teaching a solution of calcium lactobionate being effective in killing microorganisms in food (Roselle); and in combination with the primary reference, discloses the presently claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LELA S. WILLIAMS whose telephone number is (571)270-1126. The examiner can normally be reached on Monday to Thursday from 7:30am-5pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Humera Sheikh can be reached on 571-272-0604. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Humera N. Sheikh/
Supervisory Patent Examiner, Art Unit 1789

/LELA S WILLIAMS/
Examiner, Art Unit 1789

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